(d) *Exemptions.* (1) Exemptions or modifications from the requirements under paragraph (b) of this section shall be made only upon written approval by the Director, Center for Biologics Evaluation and Research (HFB–1).

(2) Nonlicensed source material suppliers are exempt from drug registration.

(Approved by the Office of Management and Budget under control number 0910–0124 for paragraph (b)(2)(iii) and control number 0910–0161 for paragraph (c))

[38 FR 32100, Nov. 20, 1973, as amended at 49 FR 25432, June 21, 1984; 49 FR 31395, Aug. 7, 1984; 55 FR 11014, Mar. 26, 1990]

§ 680.2 Manufacture of Allergenic Products.

(a) *Extraneous allergenic substances.* All manufacturing steps shall be performed so as to insure that the product will contain only the allergenic and other substances intended to be included in the final product.

(b) *Cultures derived from microorganisms.* Culture media into which organisms are inoculated for the manufacture of Allergenic Products shall contain no allergenic substances other than those necessary as a growth requirement. Neither horse protein nor any allergenic derivative of horse protein shall be used in culture media.

(c) *Liquid products for oral administration.* Liquid products intended for oral administration that are filled in multiple dose final containers shall contain a preservative in a concentration adequate to inhibit microbial growth.

(d) *Residual pyridine.* Products for which pyridine is used in manufacturing shall have no more residual pyridine in the final product than 25 micrograms per milliliter.

(e) [Reserved]

(f) *Records.* A record of the history of the manufacture or propagation of each lot of source material intended for manufacture of final Allergenic Products shall be available at the establishment of the manufacturer of the source material, as required by § 211.188 (OMB control number 0910–0139) of this chapter. A summary of the history of the manufacture or propagation of the source material shall be available at the establishment of the manufacturer of the final product.

[38 FR 32100, Nov. 20, 1973, as amended at 49 FR 25433, June 21, 1984]

§ 680.3 Tests.

(a) *Identity.* When a specific identity test meeting the provisions of § 610.14 of this chapter cannot be performed, the manufacture of each lot shall be separated from the manufacture of other products in a manner that will preclude adulteration, and records made in the course of manufacture shall be in sufficient detail to verify the identity of the product.

(b) *Safety.* A safety test shall be performed on the contents of a final container of each lot of each product as prescribed in § 610.11 of this chapter, except for the following:

(1) For lots consisting of no more than 20 final containers or 20 sets of individual dilutions, or where the final container contains no more than one intended human dose, the safety test need not be performed on the contents of a final container provided the safety test is performed on each lot of stock concentrate and on each lot of diluent contained in the final product. Only stock concentrates and diluents which have passed the general safety test shall be kept in the work areas used for the manufacture of Allergenic Products. A stock concentrate is an extract derived from a single allergenic source and used in the manufacture of more than one lot of product, and from which final dilutions or mixtures, are prepared directly.

(2) For powders for scratch tests, a sample shall be suspended in a suitable diluent and injected into each animal, and the sample size shall be the single human dose recommended.

(c) *Sterility.* A sterility test shall be performed on each lot of each Allergenic Product as prescribed in § 610.12 of this chapter, with the following exceptions:

(1) When bulk material is not prepared, the sterility test prescribed for bulk material shall be performed on each container of each stock concentrate at the time a stock concentrate is prepared, and the test sample shall be no less than 1 ml. from each stock concentrate container.